UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 33

Application Number: 09/182,645
Filing Date: October 30, 1998
Appellant(s): LI ET AL.

Mark J. Pino
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 10, 2002 and supplemental appeal brief filed February 12, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existance of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief and supplemental brief is correct.

(7) Grouping of Claims

The rejection of claims 46-49 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

CN patent 1077644	Wang	October 27, 1993
CN Patent 1113711	Ning	December 27, 1995
JP Patent Application 3-205402	Tanuma	September 6, 1991
JP Patent Application 4-13684	Tanuma	January 17, 1992

Wen et al. " Ginseng root prevents learning disability and neuronal loss in gerbils with 5-minute forebrain ischemia," Acta Neuropathol. Vol. 91, pages 15-22, 1996.

Kim et al. Biosis Abstract, AN 1988268183, 1988.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 46-49 are rejected under 35 U.S.C. 112, first paragraph

2. Claims 46-49 are rejected under 35 U.S.C. 102(b)

3. Claims 46-49 are rejected under 35 U.S.C. 103(a)

These rejections are fully set forth in prior office action, paper No. 29.

(11) Response to Argument

1. Appellants argue that the claimed invention is enabled for "PARG inhibitors" because the specification shows structurally unrelated compounds are found to be PARG inhibitors and are useful in the claimed invention, and the assay method for PARG inhibitors is disclosed in the specification. Appellants assert that there is no need of undue experimentation to practice the

claimed invention. This argument is not probative. The instant specification fails to provide information, or proper written description that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the employment of "PARG inhibitor" and provides no guidance, direction as to the structural features required for a PARG inhibitor. There are millions of compounds, if not more, known in the art; a much larger number of compounds presented naturally are not fully characterized structurally and biologically; plus numerous compounds are created daily by people in the art. The breadth of the claims essentially encompasses all the compounds, known or unknown, presented, or yet to be created, which possess PARG inhibiting function. As appellants argued in the appeal brief, there is absolutely no disclosed or known correlation between the functions herein claimed and compound structure. Finding the PARG inhibitors

from these vast number of compounds is purely a trial and error process. In summary, the specification or the claims do not provide enough information to lead a person skilled in the art to all the compounds encompassed thereby. Appellants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation.

Appellants further argue that relied on *Lilly* and *General Electric* cases cited by examiner is misplaced with relation to the present application. This rebuttal argument asserts both cases are directed to products, not a method as herein claimed, and the structure of the product or composition in both cases was directly the point of novelty. The examiner strongly disagrees; In both *Lily* and *General Electric*, the court did not draw a distinction between a product and a method. The issue is whether a functional description of a subject matter employed in the claim is proper. As discussed above, the functional description of the compounds employed in the claimed invention fails to lead a person skilled in the art to all the compounds encompassed thereby, which are necessary to practice the claimed invention.

2. Appellants' rebuttal arguments regarding the rejections under 35 U.S.C. 102(b) over Wang, Ning and Tanuma are unconvincing. The instant claims are directed to a method of using a composition *comprising* a natural product which is commonly found in plant materials, to include those old and well-known frequently used herb products disclosed in the cited prior art. As stated in the office action paper No. 29 "Wang teaches method of treatment of diabetes comprising administering ginseng, in the form of tea to a patient. See the abstract. A tea bag containing 1.8 gram of ginseng powders. (See page 3, the application example of the English translation"). Appellants do not dispute examiner's claim that treating diabetes in a patient would read on treating neural or cardiac tissue damage such as reperfusion injury. Yet, appellants argue

that Wang's teaching a ginseng composition "suitable for diabetes patient," is solely because the said composition is free of sugar, and not for its well-known therapeutic properties. These rebuttal arguments ignore Wang's express statement that the composition "is particularly suitable for diabetes patients, with therapeutic and preventing effects," (see the abstract). Appellants further attack the credibility of Wang's teaching (foot note, page 5 of the appeal brief) by stating the teaching is generic, undefined and unsupported, and therefore is not credible to one of ordinary skill in the art. This attack has absolutely no merit. One of ordinary skill in the art would have taken the full value of Wang's teaching, absent evidence to the contrary. Appellants provide no evidence to discredit Wang's teaching. Specifically, appellants provide no contradicting evidence showing ginseng fails to provide a therapeutic effects on diabetes.

3. As to Ning's teaching, the examiner states "Ning teaches method of treatment of ischemia comprising administering ginseng in the form of tea to the patient. See the abstract. A tea bag weigh about 15 g, which contains about 1% of ginseng extract." (See, page 2, the last paragraph bridging to page 3, the third paragraph of the English translation). Appellants make an "*ad hominem*" attack on Ning reference, alleging Ning's teaching as "unsupported and mysterious." As discussed above, this attack is without merit. Appellants further state that "Ning fails to disclose the elements of claim 46, i.e., *therapeutically* treating neural or cardiac tissue damage resulting from disease or condition." (Emphasis added). These arguments are confusing as to the "therapeutically treating" encompassed thereby. Claim 46 reads "A method of treating neural or cardiac tissue damage resulting from a disease or condition in a mammal in need thereof, comprising administering to said mammal a therapeutically effective amounts of an inhibitor of poly(ADP-ribose)glycohydrolase," wherein the therapeutically effective amounts are

0.1 to 100 mg/kg of body weight a day (See page 40, lines 12-15 in the specification) (5-10,000 mg per day for persons with body weight 50-100 kg). Appellants have not shown that the amounts of lignin glucoside in the dosage taught by Wang or Ning would not fall in this range. In view the fact that ginseng is a valid source of lignin glucoside, the dosage form of Wang, or Ning, would have reasonably expected to contain such amount of lignin glucoside. Appellants' arguments that the Ning's composition is not for treating but for "temporarily receive certain body stimulating health effects" is neither clear no convincing. A person having myocardial ischemia and administering the composition as taught by Ning would have effectively practiced the claimed invention.

1. Appellants argue any ginseng contains at least dozens of distinct compounds/agents in any one type of ginseng, and there are many type of ginseng. Thus, one of ordinary skill in the art would not known which particular ginseng component may have health benefit, or which components is PARG inhibitor, as herein claimed. These arguments are not persuasive. It is must noted that lignin glucosides are present in most plants, indicating that lignin glucoside is a common components of plant materials. As stated above, a patient administering the composition as taught by Wang, or Ning, would have effectively practiced the claimed invention. Identifying the active ingredients, or a particular biological mechanism for an old and well-known method is not seen to render the old method patentable. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

The examiner states in the last office action that "Tanuma teach that ginseng hot water extract containing the lignin glycoside herein. See page 5, lines 2-4, the embodiment 1 at page 5, and page 12 in JP 3-205402 the translated copy. Therefore the claimed method herein read on the method taught by Wang and Ning." Appellants argue that Tanuma, Wang and Ning use completely different extraction procedure for ginseng, and only Tanuma's provides a *pure* form of lignin glucoside for possible therapeutic use. It is noted that the features upon which applicant relies (i.e., pure form of lignin glucoside) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, with respect to Wang reference: note Wang employs the whole ginseng, including the solids remaining after water extract (D) (See the application samples). All the fractions are pulverized and subjected to boiling water extraction to produce "tea".

Regarding Ning's teaching; the dosage for of Ning is a 15 grams which contains about 1% of ginseng extract, which is about 150 mg. If the skilled artisan that lignin glucoside is a small portion of the extract, e.g., 5%, it would have met the claimed limitation.

Appellants argue that "claims 46-49 are not claiming the old "thing" (e.g., lignin glycoside) referred to *In re Swinehart* on the basis of newly discovered properties of functions' rather, applicants are claiming (see, e.g., claim 46) PARG inhibitors that are used in novel method of treating neural or cardiac tissue damage..." The examiner notes that lignin glucoside is the elected species of PARG inhibitor (paper No. 9). As to the employment of functional limitation "PARG inhibitor," see the rejection under 35 U.S.C. 112 first paragraph set forth in paper No. 29 and the discussion above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, this teaching, suggestion and motivation are found in both the references and in the knowledge generally available to one of ordinary skill in the art. Particularly, Ning and Wang references teach that a ginseng composition is useful for treating, *inter alia*, ischemia and diabetes. Tamura references teaches that ginseng comprises PARG inhibitors herein employed, Wen and Kim particularly teach ginseng is useful for treating ischemia and or reperfusion injury (diabetes causes reperfusion injury). One of ordinary skill in the art would be motivated to employ ginseng for treating ischemia or diabetes since ginseng is particularly useful for treating ischemia and reperfusion injury.

Appellants argue Kim teaches whole Ginseng, and does not identify the PARG inhibiting components. Note the claim is directed to a composition comprising PARG inhibitor. Tamuna shows that ginseng comprise the inhibitor. Appellants further argue that Wen reference teaches away from the instant claims because Wen identifies Rb1 as an active ingredient for treating ischemia. The examiner disagrees. Wen indeed identifies Rb1 as one of the active ingredient against ischemia. However, Wen does not exclude the presence of other active ingredients in ginseng. See page 20. In fact, Wen shows that whole ginseng is more effective against ischemia than Rb1. (see Fig. 2 at page 17). Such teaching actually would have motivated ordinary skill in

the art to use whole ginseng, which, according to Tamura, comprises PARG inhibitor (page 21, the last two paragraph in Wen).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Shengjun Wang
Examiner
Art Unit 1617

April 18, 2003

Conferees

RUSSELL TRAVERS
PRIMARY EXAMINER

THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200 1600

NIXON & VANDERHYE P.C.,
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201